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In Re: Patent Term Extension
Application for
U.S. Patent No. 5,795,911

NOTICE OF FINAL DETERMINATION
AND
REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. 5,795,911, claims of which cover the human drug product VEREGEN®, also known as POLYPHENON® E, (kunecatechins) Ointment 15%, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,300 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period.

Applicant also has applied for patent term extension of U.S. Patent No. 5,968,973 (FDA Docket No. 2007E-0458) based on the regulatory review period for the human drug product VEREGEN®, also known as POLYPHENON® E, (kunecatechins) Ointment 15%.

When patent term extension applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance, unless applicant elects a different patent. In the absence of an election by applicant within one month of the date of this notice, and in accordance with 37 CFR 1.785(b), the application for patent term extension in U.S. Patent No. 5,968,973 will be denied. Accordingly, the application for patent term extension of the patent having the earlier date of issuance will be granted, i.e., a certificate of extension will be issued to U.S. Patent No. 5,795,911. In the absence of a request for reconsideration and if U.S. Patent No. 5,795,911 is elected, the Director will issue to the applicant a certificate of extension, under seal, for a period of 1,300 days in U.S. Patent No. 5,795,911.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of June 3, 2008 (73 Fed. Reg. 31697), would be 1,697 days. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,605 - 5) + 397 \\ &= 1,697 \text{ days (4.6 years)}\end{aligned}$$

Since the regulatory review period began August 14, 1998, before the patent issued (August 18, 1998), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period, in accordance with 35 U.S.C. § 156(c). (From August 14, 1998, to and including August 18, 1998, is 5 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,697 days, would extend the patent from April 10, 2017, to December 2, 2021, which is beyond the 14-year limit (the approval date is October 31, 2006, thus the 14 year limit is October 31, 2020). The period of extension is thus limited to October 31, 2020, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, April 10, 2017, to and including October 31, 2020, or 1,300 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,795,911
Granted:	August 18, 1998
Original Expiration Date ¹ :	April 10, 2017
Applicant:	Shu Jun Cheng et al.
Owner of Record:	Mitsui Norin Co., Ltd. & Cancer Institute (Hospital), Chinese Academy of Medical Sciences
Title:	Composition for Treating <i>Condyloma Acuminata</i>
Product Trade Name:	VEREGEN®, also known as POLYPHENON® E, (kunecatechins) Ointment 15%
Term Extended:	1,300 days
Expiration Date of Extension:	October 31, 2020

Any correspondence with respect to this matter should be addressed as follows:

¹Subject to the provisions of 35 U.S.C. § 41(b).

By mail: Mail Stop Hatch-Waxman PTE By FAX: (571) 273-7728
Commissioner for Patents
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Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to Raul Tamayo at (571) 272-7728.



Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: VEREGEN®, also known as
POLYPHENON® E,
(kunecatechins) Ointment 15%
FDA Docket No.: 2007E-0460

Attention: Beverly Friedman